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F-1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K001896

1. Submitter's Identification:

Sponsor/Manufacturer

GC Corp. D.b.a. Suzuken Co., Ltd.
Head Office:
8, Higashikataha-Cho
Higashi-Ku, Nagoya 461-8701
Japan
Telephone: (052) 950-6327
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Consultant/Contact

mdi Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, NY 11021
Telephone: 516-482-9001
Facsimile: 516-482-0186

Primary Contact: Carolann Kotula
Vice President RA/QA

Date Summary Prepared: June 12, 2000

2. Name of the Device:

Proprietary Name:	Kenz ECG 108 Single Channel Digital Electrocardiographs Kenz ECG 110 Single Channel Digital Electrocardiographs with ECG preview display.
Common/Usual Name:	Electrocardiograph, ECG, ECG monitor, or ECG recorder
Classification Name:	Electrocardiograph

3. Predicate Device Information:

The Kenz ECG 108/110 are substantially equivalent to the Kenz ECG 303 which was legally marketed in the United States by Cambridge Medical Instruments, Inc. under K896227. The subject devices are different from the predicate in that they may be battery operated, and they are single channel devices, where the ECG 303 is a three-channel device. There are other minor differences, such as weight.

4. Device Description:

Both the EKG 108/110 are compact, portable, single-channel electrocardiographs. They are housed in gray plastic cases that include a carrying handle. The overall dimensions of both units are identical, however, the ECG 110 includes a 5.7" (diagonal) LCD panel that displays the ECG waveform, or messages related to device settings, or error conditions. The ECG 108 has only a two line LCD with the messages.

The units are powered from the AC line or from an internal nickel metal hydride battery that recharges automatically when line power is available.

The Units use a standard 12-lead patient cable that meets FDA requirements for patient protection against electrical shock. The units can run manually, to generate a cardiogram of a specific ECG lead; the operator can also select one of several automatic lead-switching sequences. Hum, drift, and muscle tremor filters can be selected.

The single-channel recorder uses preprinted rolls of thermally sensitive paper and a thermal array printing mechanism. Three trace widths are selectable by the operator – thin, standard, and thick. The operator may also select from several recording speeds and sensitivities, and automatic gain is also available. The gain, paper speed, and filters settings are printed along the edge of the paper. There is a 2-second delay between the occurrence of a signal, and its recording on the chart, or display on the LCD.

5. Intended Use:

The Kenz ECG 108/110 are intended to detect, display, and record the electrical signals associated with cardiac activity, and display and print a graphic recording of voltage vs. time. The device is used to assist in the diagnosis of cardiac abnormalities, and reveal trends or changes in heart function. The devices are intended to be used by trained medical personnel in a clinic or hospital environment.

6. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Performance testing

The Kenz ECG 108 and 110 were tested by an independent laboratory to show conformance with applicable portions of ANSI/AAMI EC- 11, 1991, ANSI/AAMI EC- 13 – 1992, and relevant FDA Guidance Document. Performance, safety, and environmental testing was completed, and the samples passed all tests.

Electrical Safety

Electrical Safety Testing to the Standard for Medical Electrical Equipment (JIS T 1001, T 1002, 2nd Edition), and AAMI/ANSI E11 were conducted on both the Kenz ECG 108 and 110. Both units passed the testing.

Electromagnetic Compatibility

EMI and EMS testing was conducted to EN 60601-1-2, 1993 by an independent laboratory. Both units passed the testing.

7. **Discussion of Clinical Tests Performed:**

No clinical tests were performed

8. **Conclusions:**

The Kenz ECG 108 and 110 are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 8 2001

Ms. Carolann Kotula
Official Correspondent for Suzuken Co. Ltd.
Vice President RA/QA
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K001896
Trade Name: Kenz ECG 108/110
Regulatory Class: ~~II~~ ~~(two)~~
Product Code: 74 DPS
Dated: October 16, 2000
Received: October 18, 2000

Dear Ms. Kotula:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior ~~to May 28, 1976,~~ the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Stephen Rhodes

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K001896

Device Name: Kenz ECG 108/110 Single Channel Electrocardiograph

Indications For Use: The Kenz ECG 108/110 are intended to detect, display, and record the electrical signals associated with cardiac activity, and display and print a graphic recording of voltage vs. time. The device is used to assist in the diagnosis of cardiac abnormalities, and reveal trends or changes in heart function.

The devices are intended to be used by trained medical personnel in a clinic or hospital environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001896

Prescription Use X **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**